REMARKS

Applicants respectfully request reconsideration of the present application.

I. Disposition of the claims

Claims 1-12 are pending. No claim is canceled. Claim 1 is proposed to be currently amended as shown. The amendment is believed allowable under Rule 116(b)(2) (better form for appeal). Support for the amendment is in the specification as filed, e.g., paragraphs 2-5. No new matter has been added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate status identifier.

II. Obviousness rejection

A. Specific comments traversing this rejection

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menzi et al. (6,056,949), in view of Nissenson et al. (The Western Journal of Medicine, 1979, 13 1, pp. 277-284), Debregeas et al. (4,960,596), De Long et al. (6,030,621) and DeBregeas et al. (U.S. Patent No. 6,228,395). Office action dated Mar. 8, 2007, p. 4. The Examiner states that "Menzi et al. do not teach mannitol specifically," Office action dated Mar. 8, 2007, p. 5, but urged that mannitol is known, Office action dated Mar. 8, 2007, p. 5 ("Nissenson et al., teach mannitol is made from the carbohydrate, or sugar, dextrose (p. 277)."), and that a sugar is a sugar regardless of its type:

Mannitol is a modified sugar and as such, it is reasonably expected that a composition of <u>any sugar</u>, e.g. sucrose from the composition of Menzi et al., would yield the same composition comprising a sugar substance as recited in the instant claim 2 [which recites mannitol by name].

Office action dated Mar. 8, 2007, p. 5 (emphasis added).

Applicants respectfully maintain the reasons for traversal here. It is believed that the Examiner and Applicants will have to "agree to disagree" regarding the effect of the restriction requirement discussed of record. Rather than dwell on this impasse, Applicants propose the present amendment to claim 1, which is believed to avoid the remaining reasoning for the rejection.

More specifically, Menzi teaches granules containing a flavorant or odorant substance, which can be vegetable, obtained by granulation of solid particles (for example sugar, or a more complex product, such as fruit or vegetable powder, or salt) with the help of an emulsion containing such odorant or flavorant element (Col. 2, lines 6 - 27 and figure 1). The granules of Menzi can be over coated with a protective coating, such as PVP (Col. 2, lines 39 - 48). Nissenson is cited because it teaches neutral core based on sugar and starch. Debregeas I is cited because it teaches a controlled release layer based on ethylcellulose. Debregeas 2 is cited because it teaches a slow release layer based on HPMC. Delong is cited because it teaches a gingko biloba extract. (Applicants noted that the Examiner mentions elements which is believed irrelevant or the significance has not been appreciated (see "picolinate" in the 3rd paragraph of page 7 of the final Office action)).

Applicants respectfully submit that the granules of Menzi are not intended for a pharmaceutical use. Menzi relates to aromatic granules. The applications taught by Menzi are: tea bags, instant drink powder, chewing gum, hard and chewable sweets, or ice cream with chocolate coatings (see example 6). The aromatic granules of Menzi are used as a flavorant vector incorporated into products to give a flavor to said product. Menzi does not teach nor suggest that the granules may be used per se as a formulation having a pharmaceutical activity. In other words, Menzi fails to teach or suggest the *pharmaceutical formulation in the form of granules* as recited in claim 1.

The other references are silent in regards to the *pharmaceutical formulation in the form of granules* as recited in claim 1.

For these reasons, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine all these elements together to make the *pharmaceutical* formulation in the form of granules as recited in claim 1.

Conclusion

It is believed that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

FOLEY & LARDNER LLP Customer Number: 22428

Telephone: (202) 295-4166

Facsimile: (202) 672-5399

Sean A. Passino

Attorney for Applicants Registration No. 45,943